Rec'd PCT/PTO 29 DEC 2004

PCT/FR2003/002050

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H52437 CAS9	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/002050	International filing date (*day/month/year*) 02 juillet 2003 (02.07.2003)	Priority date (*day/month/year*) 03 juillet 2002 (03.07.2002)
International Patent Classification (IPC) or national classification and IPC G01N 33/569, 33/96		
Applicant UNIVERSITE DE LA MEDITERRANEE (AIX-MARSEILLE II)		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 décembre 2003 (17.12.2003)	03 May 2004 (03.05.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/002050

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☒ the description:

pages 1-14, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-14, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:

pages 1/3-3/3, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12, 14	YES
	Claims	13	NO
Inventive step (IS)	Claims		YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims		NO

2. Citations and explanations

1. Reference is made to the following document:

D1: Garrote et al., A novel visual immunoassay for coeliac disease screening, European Journal of Clinical Investigation, 1999, 29(8), 687-699

2. The following document is not an international search report citation; a copy of the document is appended:

D1: DE 100 00 322 A (BIOSENS GES. FUR DIAGNOSTIKA) 27 July 2000

3. The subject matter of claims 1 to 12 is novel (PCT Article 33(2)): no document describes a serological diagnostic method characterized in that the presence of human serum in an analysis sample is established by detecting whether human immunoglobulins react with an antigen containing the A protein of *Staphylococcus aureus* (claim 1).

4. The subject matter of independent claim 13 is not novel (PCT Article 33(2)).

a. D1 (page 698, left-hand column, paragraph 5, to right-hand column, paragraph 1) describes a human immunoglobulin detection method based on the reaction with the marked *S. aureus* A protein, the method involving the use of the A protein and colloidal gold, enabling the A protein : immunoglobulin complex to be detected. The subject matter of the claim is defined only by the components of the kit explicitly mentioned in the claim.

b. On the other hand, the subject matter of dependent claim 14 is novel because D1 describes neither a solid substrate on which the A protein is deposited nor the presence on the solid substrate of a second antigen corresponding to a microbial agent to be detected.

5. The subject matter of claims 1 to 14 is not inventive (PCT Article 33(3)).

a. D2, which represents the closest prior art, describes a serological diagnostic method in which the presence of antibodies specific to an infectious microbial agent in a test sample is detected. The method is characterized in that the presence of human serum in the sample is established by detecting whether human immunoglobulins react with antibodies specific to the human immunoglobulins.

b. The difference between the present application and D2 is that, in the application, the presence of human serum in the test sample is established by detecting whether human immunoglobulins react with an antigen containing the A protein of *S. aureus*. No technical effect has been demonstrated in relation

to this difference. The technical problem addressed by the application in light of the closest prior art is thus that of devising an alternative method of checking for the presence of human serum in a test sample. The proposed solution is a method based on the detection of the reaction between human immunoglobulins and the A protein of *S. aureus*. A person skilled in the art having to solve the technical problem in question would be familiar with the human immunoglobulin detection method based on their reaction with the *S. aureus* A protein (see D1, for example). Contrary to the assertions in the application (page 4, lines 22 to 25), there is no reason to assume that this reaction is not verified in infectious disease conditions. Therefore the use of the reaction between the A protein and human immunoglobulins to confirm the presence of human serum in a test sample is obvious and hence not inventive.